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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,441	05/03/2005	Tomoji Maruyama	26036-4US90PCT	9474
22850 7590 12/21/2009 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER YABUT, DIANE D				
ART UNIT 3734		PAPER NUMBER		
NOTIFICATION DATE 12/21/2009		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/511,441

Applicant(s)

MARUYAMA ET AL.

Examiner

DIANE YABUT

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-32 is/are pending in the application.
- 4a) Of the above claim(s) 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 25-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI.08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/06/2009 has been entered. Claims 2-32 are pending in this application. Claims 9-24 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-8 and 25-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diaz** (U.S. Patent No. 5,814,065) in view of **Modesitt et al.** (U.S. Patent No. 7,001,400).

Diaz discloses providing a suturing apparatus comprising a body part ("elongated member") 15 with a predetermined length having a front side part that can be inserted into a tissue of an organism from a hole and a rear portion that cannot be inserted into

said organism having a portion ("tip") **36**, two hollow needle members **34** that are accommodated in a portion **18** inside said body part rearward from said tip portion (Figure 1), a needle operation portion **60** for advancing said needle members toward said tip portion from a side surface of said body part (Figure 4), two openings (extreme rear-most openings of needle operation portion **60**) disposed at a rear-most portion of said body part that communicate with lumens of said two hollow needle members, wherein said tip portion has two needle member receiving portions (either end of **38** in Figures 6-7) for receiving a distal end of one of said hollow needle members and that of the other of said hollow needle members respectively pressed out of said body part, and a connection duct ("needle lumen portion") **38** communicating with said two needle member receiving portions, and one continuous duct for a suturing thread **70** is formed to range from one of said two openings to the other of said openings through one of said lumens of one of said two hollow needle members, through said connection duct of said tip portion, and through the other of said lumens of the other of said two hollow needle members, when said two needle member receiving portions receive said hollow needle members respectively at a same time (Figures 4, 6-7). A suturing member can be inserted into said duct for a suturing thread, said suturing member including a guide portion linearly formed of an elastic material (length of "coil") **76** and a suturing thread portion **70** provided on said guide portion and the tip portion has a thread pull-out slit (on external surface of **36** near **38**) extending from an upper surface thereof and communicating with said two needle member receiving portions and said connection duct (Figure 1). An urging member **68** urges said needle member operation portion or

said hollow needle member rearward and a stopper (wide, rear portion of **60**) configured to stop said hollow needle members at a position pressed by said needle member operation portion (Figure 4).

The tip portion is inserted into a blood vessel **14** from a penetrated hole, the hollow needles are advanced to the tip portion and penetrate through the blood vessel, and the suturing thread **70** is passed from a proximal end of one of the hollow needles through the lumen of the hollow needle, through the needle receiving portion, through the connection or communication duct **38** in the tip portion, through the other needle receiving portion, through the lumen of the other hollow needle, and to a proximal end of the other hollow needle, and returning the hollow needle members into the body part and pulling the suturing apparatus out of the puncture site and leaving the thread (Figures 4, 6-9).

Diaz discloses the claimed invention except for the tip portion being a rotary portion rotatably supported to a front end of said body part, rotating the rotary portion in the blood vessel until the body part becomes oblique at a predetermined angle with respect to an axis of the rotary portion, returning the rotary portion back to an initial position. Diaz also lacks a rotary portion towing wire, a rotary portion side-surface opening to receive a supporting pin on said body part, or a rotation angle restriction function.

Modesitt et al. teach a suturing apparatus having a rotary portion ("articulatable foot") **24** that is rotatably supported to a front end of a body part ("shaft") **12**, that may be rotated at an oblique angle during suturing and returned back to an initial position in

line with the longitudinal axis of the shaft (Figures 6A-6C). A rotary portion towing wire ("foot actuation wire") **32** extends inside said body part and is fixed to said rotary portion at one end thereof (Figure 5), wherein said body part has a supporting pin **60** for rotatably supporting said rotary portion **24i**, said rotary portion has a side-surface opening ("slot") **62** for receiving said supporting pin, formed long and axially extending to allow sliding of said supporting pin (Figures 8A-8C; col. 9, lines 22-30). The rotation angle restriction function permitting a rotation of said rotary portion between a state in which said rotary portion is on an approximate extension line of an axis of said body part and a predetermined angle less than 90 degrees may be considered to be the length of the side-surface opening. Although Modesitt et al. does not expressly restrict the rotation to be at a predetermined angle less than 90 degrees, it would have occurred to one of ordinary skill in the art to limit the range of movement since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotary portion to Diaz, as taught by Modesitt et al., in order to provide more flexibility of movement in positioning the tip portion to the vessel wall, while still avoiding dilation of the puncture (col. 4, lines 1-17).

Response to Arguments

4. Applicant's arguments with respect to claims 2-8 and 25-32 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

Art Unit: 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734